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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,711	04/08/2004	Larry A. Gilbertson	MONS:140US	1699

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EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	

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03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,711	GILBERTSON ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *13 and 19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 14-18 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Response filed on 7 December 2007.

2. Those rejections or objections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

4. Claims 13 and 19-23 remain withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 24 October 2006.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

6. The Examiner has required restriction between product and process claims. The Examiner considers pending claim 20 as directed to a process of using the elected product in the instant Application, and may be eligible for rejoinder if the elected invention is found to be allowable. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable

product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 103

7. Claims 1-12 and 14-18 and 24-26 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Heim *et al* (U.S. Patent Application Publication US 2003/0188345 A1, filed 28 June 2001) in view of Lange *et al* (U.S. Patent 5,939,539) and Ebinuma *et al* 1997 (Proc. Natl. Acad. Sci. USA 94: 2117-2121). This rejection is repeated for the reasons of record set forth in the previous Office action mailed 4 September 2007. Applicants' arguments filed 7 December 2007 have been fully considered but are not found to be persuasive.

Applicants argue that the claims are not rendered obvious by Helm et al. in view of Lange et al. and Ebinuma et al, in that Helm et al. do not teach a plant cell non-lethal negative selectable marker gene within the meaning of the claims, and neither Lange nor Ebinuma cure this defect, codA is described at paragraphs 23 and 25 of Heim as a marker gene that may be used in a combined positive/negative selective scheme as described by Gallego et al. (Plant Mol. Biol. 39:83-93, 1999). Applicants argue that Gallego describes codA as a lethal marker gene, i.e. conferring sensitivity to added 5-fluorocytosine (5-FC). Applicants argue that codA may be described as a conditional lethal marker gene, in that its lethal effect requires the presence of the added 5-FC, as noted in the present Specification, for instance at page 3, lines 13- 20, and at page 30, lines 10-16, while in the absence of 5-FC codA does not function as a marker gene (paragraph spanning pages 6-7 of the Response). These arguments are not found to be persuasive. The problem to be solved, and the basic structure claimed in the instant application had been previously taught by Heim et al. It is clear from the teachings of Heim et al that the codA gene can be used as a negative selectable marker which is involved in metabolite interference (nucleotide synthesis in the presence of 5-FC). The *ipt* gene taught by Ebinuma et al.

was widely recognized in the instant art as involved in plant cytokinin/hormone biosynthesis pathway, and Ebinuma et al. teaches that a negative selectable phenotype is present in plants transformed therewith.

Applicants argue that nowhere does Heim discuss use of a non-lethal negative selectable marker gene. Applicants argue that the terms "lethal" or "non-lethal" are not found in Helm. Applicants argue that the term "selectable" is not found in Helm. Applicants argue that the term "marker" is found throughout Heim; however it is only used in the context of lethal or conditional lethal markers. Applicants argue that there is no motivation for one of skill in the art to combine these references. Applicants argue that this assertion that Helm motivates the use of any non-lethal selectable markers, let alone "other" non-lethal selectable markers, is unsupported, and represents hindsight reasoning. Applicants argue that a *prima facie* case of obviousness has therefore not been established. Applicants argue that even if the references were properly combined, the addition of the cited Lange and Ebinuma references does not cure the defect in Heim. Applicants argue that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art (page 7, 2nd paragraph of the Response). In response to Applicants' arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The fact that Heim does not use a specific term does not obviate a finding of obviousness. As stated in the previous Office action, Heim had identified the problem to be solved, that being the undesirability of introducing vector sequences when transforming plants. Heim teaches a

solution, making a T-DNA plasmid having a selectable marker outside of the left T-DNA border that if introduced into a transformed plant cell can be used to select against (negative selectable marker). Heim also teaches using the *pat* gene that is a transgene of agronomic interest and a selectable herbicide resistance marker (see Figure 2). KSR forecloses the argument that a **specific** teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, -- USPQ2d --, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396).

Applicants argue that Lange does not describe use of gibberellin 20-oxidase (GA 20 oxidase) as a selectable marker, including as a non-lethal selectable marker, rather, use of the GA20 oxidase is in the context of its effect on agronomic or horticultural characteristics. Applicants argue that regarding Ebinuma et al, Applicants note that (loss of) an already present *ipt* gene is being used as a screenable marker, and not as a non-lethal negative selectable marker. Applicants argue that some confusion regarding the term "selection" may have arisen. Applicants argue that as typically used in the art, a "selectable" marker is distinguished from a "screenable" marker, e.g. in that in the first instance the presence or absence of the marker interferes with the ability of a cell or organism to develop or survive and is thus, under certain conditions or at some developmental stage, biochemically or genetically lethal. Applicants argue that screenable markers allow for development of a cell or organism, while providing a phenotype that distinguishes cells possessing the marker from those which do not, such as a visible phenotype. Applicants argue that a skilled worker may then "select" (i.e. more properly screen for or score) a cell or organism based on this phenotype, but this sense of the term is clearly distinct in the art from its use in the first instance. Applicants argue that these terms are used differently by the

Action (e.g. when the Action at page 6, 1st full paragraph, states that Ebinuma combined with Heim teach that the *ipt* gene produces a "selectable phenotype") and by Ebinuma, as compared with their use in the present Specification, and in the claims as read in view of the Specification. Applicants argue that Ebinuma is describing a screenable phenotype, and the only "selection" is occurring is at the hands of the experimenter (page 8 of the Response). These arguments are not found to be persuasive. Applicants argue the teachings of Lange individually and apart from the teachings of the prior art as a whole. Lange teaches a phenotype that can be used as a negative selectable trait in a transgenic plant. Applicants' arguments concerning the teachings of Ebinuma had been addressed in the previous Office action at page 6. Applicants' attempt to distinguish between a "selectable" marker and a "screenable" marker is not found to be persuasive. First the instant specification does not make such a distinction, and second it would have been obvious to one of ordinary skill in the instant art that a "selectable" marker and a "screenable" marker can be interchangeable in many instances. Both selection and screening occurs in the hands of the experimenter by way of the experimental design.

Applicants argue that Ebinuma teaches away from use of *ipt* as a selectable marker gene (i.e. as in the first instance above), by noting that transgenic plants possessing the *ipt* gene are unable to regenerate normally (i.e. to develop roots). Applicants argue that Ebinuma describes use of a system wherein loss of the *ipt* marker, via Ac transposition and deletion, is detectable (i.e. screenable or scorable), but is not being genetically or biochemically "selected" as the term "selected" is used in the present Specification (page 9, 1st paragraph of the Response). These arguments are not found to be persuasive. Applicants argue the teachings of Ebinuma individually and apart from the teachings of the prior art as a whole. Ebinuma explicitly teaches

using a chimeric *itp* gene as a selectable marker for transformation in the Abstract at page 2117. Ebinuma teaches a selectable phenotype when the *ipt* gene is present in a transgenic plant cell in Fig 2 on page 2118. Ebinuma does not explicitly teach away from using the *ipt* gene as a negative selectable marker.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is **(571) 272-0799**. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at **(571) 272-0975**. The **central FAX number for official correspondence is** 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
11 March 2008

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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